DDM
Display Date 2-17-04
Publication Date 2-18-04
Certifier D. Hawkins

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket** No. **2004N–0047]**

# Determination That Chlorthalidone Tablets and Seven Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA)has determined that the eight drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs)for the drug products, and it will allow FDA to continue to approve ANDAs for the products.

**FOR FURTHER INFORMATION CONTACT:** Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855,301–594–2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical



N 1

testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved or, (2) whenever a listed drug is voluntarily withdrawn from sale, and ANDAs that referred to the listed drug have been approved. Section 314.161(d) provides that if FDA determines that the listed drug was removed from sale for safety or effectiveness reasons, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

The holders of the applications listed in table 1 of this document have informed FDA that the drug products have been withdrawn from sale. (As requested by the applicants, FDA withdrew approval of NDA 17–503 for COMBIPRES and ANDA 60–462 for GARAMYCIN in the **Federal Register** of August 18, 2003 (68 FR 49481)).

TABLE 1.

| Application No | Drug | Applicant |
|---|---|---|
| 12–283 | HYGROTON (chlorthalidone) Tablets, 25 and 50 milligrams (mg). | Aventis Pharmaceuticals, 300 Somerset Corporate Blvd., Bridgewater, NJ 08807–2854 |
| 17–503 | COMBIPRES (clonidine hydrochloride (HCl); chlorthalidone) Tablets, 0.1 mg/15 mg, 0.2 mg/15 mg and 0.3 mg/15 mg. | Boehringer Ingelheirn Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877–0368. |
| 17–884 | CHRONULAC (lactulose) Oral Solution, 10 grams/15 milliliter (mL). | Aventis Pharmaceuticals, Inc. |
| 18–581 | SODIUM NITROPRUSSIDE Injection, 50 mg/vial. | Elkins-Sinn, Inc., Two Esterbrook Lane, Cherry Hill, NJ 08003-4099. |
| 20-058 | THIOPLEX (thiotepa) Injection, 15 mg/vial. | Immunex Corp., 51 University St., Seattle, WA 98101–2936. |
| 50–621 | SUPRAX (cefixime) Tablets, 200 and 400 mg. | Lederle Laboratories, P.O. Box 8299, Philadelphia, PA 19101–8299. |
| 50-622 | SUPRAX (cefixirne) Powder for Oral Suspension, 100 mg/5 mL. | Do. |
| 60–462 | GARAMYCIN (gentamycin sulfate) Topical Cream, 0.1 percent. | Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033. |

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list the drug products listed in this document in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. Approved ANDAs that refer to the NDAs and ANDA listed in this document are unaffected by the withdrawal of the products subject to those NDAs and ANDA. Additional ANDAs for the products may also be approved by the agency.

Dated: 2/9/04
February 9, 2004.

cd03111

**Jeffrey Shuren,**
**Assistant Commissioner** for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

**BILLING CODE 4160–01–S**

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL
Dawn P. Hawkins